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Application No.	Ref.	Date
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Applicant: Siemens Healthcare Diagnostics Inc.		

Communication pursuant to Article 94(3) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(2) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 126(2) and 131(2) and (4) EPC.

One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (R. 50(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Art. 94(4) EPC).

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Enclosure(s): 6 page/s reasons (Form 2906)
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The examination is being carried out on the **following application documents**:

Description, Pages

1, 2, 6-14	as originally filed	
3, 3a, 4, 5	filed with telefax on	27.08.2007

Claims, Numbers

1-18	as originally filed

Drawings, Sheets

1/5-5/5	as originally filed

The following documents are introduced in the examination:

D4: EP-A-1 411 346 (ROCHE DIAGNOSTICS) 21 April 2004 (2004-04-21)
D5: WO 03/056314 A (HOFFMANN LA ROCHE ; HOENES JOACHIM (DE); PACHL RUDOLF (DE); ROCHE DIAG) 10 July 2003 (2003-07-10)

D4 has been found in a search of the state of the art according to Art. 54(3) EPC: a copy is attached to the present communication. D5 has been cited in the search report.

1. Claim 1 is not clear in the sense of Art. 84 EPC.
In step A, the claim does not specify how the "reflectance constant for a test product at a first wavelength" is determined. Moreover, the difference between this reflectance constant and the "measured reflectance at the first wavelength" of step B is unclear. In step B, it is said that the "test product is loaded with the test substance". However, because the first wavelength is chosen so that "reflectance does not substantially change with the presence of a test substance", it may appear that the "reflectance constant" determined at step A and the reflectance measured at step B after contacting the test substance are the same value.
In steps A and B it is also not clear whether the "test substance" is the analyte contained in the sample or the sample itself.

In step C, confusion arises between the first "reflectance" and the "measured reflectance", because it is not specified to which wavelength each of the values corresponds.
For the purpose of examination, the claim has been interpreted on the basis of the description (see in particular par. 34).

1.1 The same objection applies to the other independent claims 8 and 15.

2. Document D4, which claims a priority date of 18.10.2002, is part of the state of the art in the sense of Art. 54(3) EPC for the present application. The subject-matter of independent claims 1, 8 and 15 is not new over the disclosures of this document.

2.1 D4 discloses:

p. 3, l. 41-42; *p. 3, l. 54-55;*	A method of correcting reflectance comprising the steps of :
p. 8, l. 40-42;	A. determining a reflectance constant for a test product (*"Eichwert", reflectance corresponding to maximum coverage*) at a first wavelength (*control wavelength*)
p. 6, l. 34-35	for which reflectance does not substantially change with the presence of a test substance;
p. 6, 31-34	B. with the test product loaded with the test substance, determining a reflectance at a second wavelength for which signal-to-noise ratio is maximized (*detection wavelength*)
p. 6, l. 34-35; *p. 8, l. 40*	and determining a measured reflectance at the first wavelength.

It is implicitly dislcosed that, to determine the extent of coverage, D4 calculates the ratio between the measured reflectance at the control wavelength and the constant representing the maximum coverage (see the linear relationship at *p. 9, l. 9-10*). Consequently, also the step of claim 1:

> C. determining a corrected reflectance as the product of the reflectance with a ratio of the reflectance constant to the measured reflectance,

is implicitly disclosed. To correct the reflectance value taking into account the extent of

coverage of the test product (*p. 3, l. 41*), the skilled person would inevitably divide the measured reflectance by the extent of coverage, which is the same calculation as in step C.
The method of claim 1 is therefore not new over D4.

2.2 The subject-matter of claim 8 is an apparatus configured to carry out the method of claim 1. Because D4 also discloses an apparatus carrying out the method (*fig. 1*), claim 8 is not new over D4 (see the same passages cited above). The same reasoning applies to the computer program of claim 15, mutatis mutandis.

3. Furthermore, the present application does not meet the requirements of Article 52(1) EPC because the subject-matter of the independent claims 1, 8 and 15 does not involve an inventive step within the meaning of Article 56 EPC.

3.1 Document D1 can be seen as the closest prior art to the subject-matter of claim 1. This document discloses:

col. 7, l. 34-36; *col. 8, l. 3-8*	a method for correcting reflectance measurements, comprising:
col. 2, l. 52-56	1) determining, by means of a correction paper pad **4**, reference reflectance values at a given a set of wavelengths;
fig. 9; *col. 8, l. 10-17*	2) determining a first wavelength *n*, at which reflectance does not substantially change with the presence of a test substance, and a second wavelength *m*, at which the signal-noise ratio is maximized;
col. 8, l. 18-29	3) at the chosen wavelengths, measuring the respective reflectance values R_{3bn} and R_{3bm} of a test pad; 4) Calculating a corrected relative reflectance value as: $R_c = (R_{3bm} R_{4n}) / (R_{3bn} R_{4m})$ (*) where R_{4m} and R_{4n} are the reference reflectance values respectively at the wavelengths *m* and *n*.

The reference reflectance at the first wavelength R_{4n} of D1 can be seen as the "reflectance constant" of step A of the method of claim 1, the measured reflectance R_{3bn} at the same

wavelength is the "measured reflectance" of step B, whereas the measured reflectance R_{3bm} at the second wavelength m is the "reflectance at a second wavelength at which the signal-to-noise ratio is maximized". Therefore, using the same symbols of D1, the corrected reflectance of claim 1 is given by the expression:

$$R'_c = (R_{3bm}\ R_{4n}) / R_{3bn} \qquad (**)$$

Comparing expressions (*) and (**), it appears that the only difference between the methods of D1 and claim 1 is that in D1 the additional step of dividing by the reference reflectance R_{4m} at the second wavelength *m* is performed, in order obtain the corrected reflectance.

3.2 In claim 1, skipping the division by R_{4m} has the technical effect of obtaining the corrected reflectance as an absolute quantity, whereas in D1 the reflectance is given as a percentage (see *col. 3, l. 52-56; col. 8, l. 11*) of the reflectance of the correction paper **4**. The problem to be solved by the invention may therefore be seen as: obtaining the corrected absolute value of the reflectance at the second wavelength *m,* instead of the corrected relative value.

3.3 It is however trivial for the skilled person, in order to solve the problem mentioned, to obtain this absolute value from the relative reflectance R_c of D1, just by multiplying R_c by the reference value R_{4m}, or by skipping the division by R_{4m} in expression (*), therefore arriving at the value R_c' as in expression (**) of claim 1.
The subject-matter of claim 1 does not therefore involve an inventive step in the sense of Art. 56 EPC.

3.4 The same argument may be followed starting from D3, which discloses the same correction algorithm of D1 (*col. 23, l. 60 - col. 24, l. 3*). In D3, the values $R_{max/\lambda}1$ and $R_{max/\lambda 2}$ represent the reference reflectance values at the first and second wavelengths respectively.

3.5 An additional reasoning to demonstrate the obviousness of the method of claim 1 may start from document D5.
This document discloses the determination of a reflected theoretical intensity I_{theo} (*p. 10, l. 20-25*) at a first wavelength at which the absorption is analyte-independent (*p. 9, l. 1-5*). A value of the reflected intensity I_{Mess} is also measured at the same wavelength, after the test

product has contacted the sample (*p. 9, l. 1-5; p. 11, l. 19-27*). These are the "reflectance constant" and the measured reflectance of claim 1 at the first wavelength. D5 then uses these parameters to correct an additive error (see *eqs. 2 and 3*) in the intensity I_{Analyt} measured at the second, analyte-dependent wavelength.

The method of claim 1 differs from D5 because the corrected reflectance is obtained by multiplying the reflectance at the second wavelength by the ratio of the other parameters, rather than subtracting an intensity change as in D5 (*eq. 3*).

The problem solved by this feature may be regarded as: correcting a multiplicative error instead of an additive one. A known cause of multiplicative errors in these measurements are, for example, variations of the height of the test product (see D1 *col. 8, l. 65 - col. 9, l. 3*).

It would be obvious for the skilled person to arrive at the method of claim 1, for solving this problem in the method of D5. If a multiplicative error K is present, it follows that:

- the measured reflectance at the first wavelength is $I_{meas} = K * I_{theo}$, and
- the measured reflectance at the second wavelength is $I_{analyte} = K * I_{corr}$

using the symbols of D5. Consequently, the skilled person would immediately obtain:

$$I_{corr} = I_{analyte} * (I_{theo} / I_{meas})$$

without any inventive effort, arriving at the scope of claim 1.

2.6 The same argument applies to the other independent claims 8 and 15.

3. None of the dependent claims appears to overcome the objections of lack of inventive step raised above.